

Atty. Docket No. 2083-2A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of )  
David F. Mark et al. ) Before the Examiner  
Serial No. 655,897 ) B. Hazel  
Filed: September 28, 1984 ) GROUP ART UNIT: 127  
For: CYSTEINE-DEPLETED MUTEINS )  
OF BIOLOGICALLY ACTIVE )  
PROTEINS )

RECEIVED

DEC 17 1985

GROUP 120

Hon. Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

I, Albert P. Halluin, declare that:

1. I am General Patent and Trademark Counsel of Cetus Corporation in Emeryville, California 94608 and am one of the attorneys of record in the above-identified patent application. I make this declaration to set forth the facts related to the permanence, availability and replacement of the deposits of plasmid pSY2501 cloned into E. coli to which the above-identified application refers. As indicated in the specification at page 19 (lines 1-10), pSY2501 was cloned into E. coli strain MM294 (page 13, lines 21-24) and was deposited with the Agricultural Research Culture Collection (NRRL) on March 30, 1983 under accession number NRRL B-15356. Further, pSY2501 cloned into E. coli strain MM294-1 was deposited with the American Type Culture Collection (ATCC) on November 18, 1983 under the accession number ATCC No. 39517 (page 20, lines 14-19).

2. I identify the following documents that demonstrate that the deposits of pSY2501 cloned into the E. coli strains meet all the requirements of applicable rules and regulations of the United States Patent and Trademark Office as to permanence, availability and replacement for deposited cultures:

212

a. Exhibit A is the correspondence between Cetus Corporation and the NRRL evidencing that the deposit given the accession number NRRL B-15356 was made on March 30, 1983 under the Budapest Treaty;

b. Exhibit B similarly documents that the deposit at the ATCC given the accession number ATCC No. 39517 was made on November 18, 1983 also under the Budapest Treaty; and

c. Exhibit C is a copy of the Budapest Treaty of International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure as published in Baxter, J.W. et al., World Patent Law and Practice, Vol 2A, Part 2, App-3-644-682 (1985) [also in 961 OG 21-36 (August 23, 1977)]. I am informed and believe that the Budapest Treaty provides for rules and regulations that meet all the substantive requirements of MPEP 608.01 (p) (C) for the deposit of microorganisms.

3. I declare that the Budapest Treaty provides in Article 4, (1) that where the culture is no longer viable that the international depository authority shall promptly notify the depositor so that a new deposit can be made [Exhibit C; App 3-647-648]. Further, I declare that Rule 10 of the Budapest Treaty (Exhibit C; App 3-674-675) obligates the depository authority to test each culture deposited for viability promptly after any deposit and at reasonable intervals thereafter; and further to issue a statement concerning the viability of the deposited microorganism to the depositor or "to any industrial property office, other authority, natural person or legal entity, other than the depositor to whom or to which samples of the deposited microorganisms were furnished in conformity with Rule 11 on his or its request, together with or at any time after such furnishing of samples." (Rule 10.2; Exhibit C; App 3-675)

4. I declare that Article 6 (2) of the Budapest Treaty requires that for the depository to qualify for the status of international depository authority it must among other criteria:

"(i) have a continuous existence;

(ii) have the necessary staff and facilities, as prescribed in the Regulations, to perform its scientific and administrative tasks under this Treaty; ...

(vii) furnish samples of any deposited microorganism under the conditions and in conformity with the procedure prescribed in the Regulations."

(Exhibit C; App 3-649-650)

5. I declare that Rule 9.1 of the Budapest Treaty provides:

Any microorganism deposited with an international depositary authority shall be stored by such authority, with all the care necessary to keep it viable and uncontaminated, for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the said authority and, in any case, for a period of at least 30 years after the date of the deposit.

(Exhibit C; App 3-674)

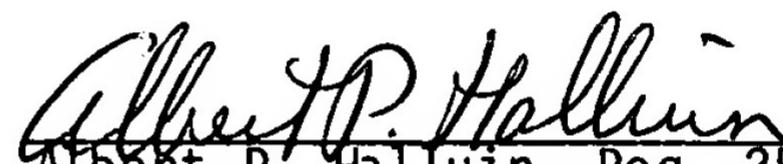
6. I declare that Rule 11.1 of the Budapest Treaty provides for the furnishing of samples to interested industrial property offices "for the purposes of a patent procedure" related to a patent "pending before that office." (Exhibit C; App 3-676). I further declare that Rule 11.3 of the Treaty provides for the furnishing of samples to parties legally entitled to receive them. (App 3-676-677).

7. I further declare that Applicants and/or Cetus Corporation shall, for the period outlined in Rule 9.1 of the Budapest Treaty and for at least the effective life of any patents issuing from the above-identified patent application, replace as promptly as practicable the above-referenced cultures should they be found to be nonviable or to have mutated.

8. Therefore, based on the attached exhibits and above statements made upon my own knowledge, information or belief, I declare that the deposits NRRL B-15356 and ATCC 39517 were made in depositories affording permanence of the deposit and ready accessibility thereto by the public, and that since May 21, 1985, when the instant application's parent issued as U.S. Patent No. 4,518,584, all restrictions on the availability to the public of the cultures so deposited were irrevocably removed.

Further, on the grounds of the above-identified exhibits and discussion, I am informed and believe that the deposits of the plasmid pSY2501 cloned into E. coli strains MM294 and MM294-1 were made and are being maintained under the applicable rules and regulations of the United States Patent and Trademark Office as to their permanence, availability and replacement. [See MPEP 608.01 (p) (C).]

9. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or document or any issuance resulting therefrom.

  
Albert P. Halluin, Reg. 25,227

Dated: December 16, 1985

CETUS CORPORATION  
1400 Fifty Third Street  
Emeryville, California 94608  
(415) 420-3414

215

# Exhibit A

H9



United States  
Department of  
Agriculture

Agricultural  
Research  
Service

North Central Region  
Northern Regional  
Research Center

1815 North University Street  
Peoria, Illinois  
61604

March 30, 1983

Dr. Angela Belt  
Cetus Corporation  
600 Bancroft Way  
Berkeley, California 46710

Dear Dr. Belt:

Enclosed is the International Receipt form BP/4 for deposits made in connection with the Budapest Treaty. The subject strain is:

<u>Name</u>	<u>Strain Designation</u>	<u>NRRL number</u>
<u>Escherichia coli</u> PSY 2501	CNCC #1533	B-15356

Sincerely,

A. J. LYONS, Curator  
ARS Patent Collection  
Culture Collection Research  
Fermentation Laboratory

Enclosure

439

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO  
Dr. Angela Belt  
Cetus Corporation  
600 Bancroft Way  
Berkeley, CA 94710

VIABILITY STATEMENT

issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITORY AUTHORITY  
identified on the following page

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY STATEMENT  
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
Name:  Ms. Angela Belt Address:  Cetus Corporation 600 Bancroft Way Berkeley, CA 94710	Depositor's taxonomic designation and accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY:  <u>Escherichia coli</u> NRRL B-15356  Date of: <u>March 30, 1983</u> 1 <input checked="" type="checkbox"/> <sup>2</sup> Original Deposit <input type="checkbox"/> <sup>2</sup> New Deposit <input type="checkbox"/> <sup>2</sup> Transfer

III. VIABILITY STATEMENT AND DEPOSITOR'S EQUIVALENCY DECLARATION

Deposit was found:  <sup>2</sup>Viable  <sup>2</sup>Nonviable on March 4, 1983 (Date)  
International Depository Authority's preparation was found viable on March 7, 1983 (Date)  
Depositor determined the International Depository Authority's preparation was  
 <sup>2</sup>Equivalent  <sup>2,3</sup>Not Equivalent to deposit on 6/21/83 (Date)

Signature of Depositor Angela Belt

<sup>1</sup> Indicate the date of the original deposit or when a new deposit or a transfer has been made.

<sup>2</sup> Mark with a cross the applicable box.

<sup>3</sup> If found nonequivalent, depositor must supply 30 lyophilized preparations made to NRRL size specifications.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST WAS PERFORMED<sup>4</sup>

V. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Agricultural Research Culture Collection (NRRL) International Depository Authority Address: 1815 N. University Street Peoria, Illinois 61604 U.S.A.	Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized official(s):  <i>Ellis J. Zorn</i> Date: <u>April 14, 1983</u>
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<sup>4</sup>Fill in if the information has been requested and if the results of the test were negative.

Mr. A.J. Lyons  
Agricultural Research Culture Collection  
1815 N. University Street  
Peoria, Illinois 61604

June 21, 1983

Dear Mr. Lyons;

Enclosed is the equivalency declaration of another of the strains that we deposited with you. I also wish to inform you that our mailing address has changed. Our main headquarters is no longer located in Berkeley. Correspondance should be addressed to us at 1400 Fifty-Third Street, Emeryville, California 94608. Also, my new phone number is (415) 420-3300.

Sincerely,

CETUS CORPORATION

Angela Belt  
Curator-Culture Collection



United States  
Department of  
Agriculture

Agricultural  
Research  
Service

North Central Region  
Northern Regional  
Research Center

1815 North University Street  
Peoria, Illinois  
61604

April 14, 1983

Dr. Angela Belt  
Cetus Corporation  
600 Bancroft Way  
Berkeley, California 94710

Dear Dr. Belt:

Enclosed is the viability statement form for:

NRRL B-15356 Escherichia coli PSY2501 (CMCC #1533)

I will send under separate cover our lyophilized preparation for this strain. As soon as you confirm the equivalency of this preparation to your original deposit; complete, sign, and return the original viability statement to me.

Sincerely,

A. J. LYONS, Curator  
ARS Patent Collection  
Culture Collection Research  
Fermentation Laboratory

Enclosure

442

Mr. A. J. Lyons  
Agricultural Research Culture Collection  
1815 N. University Street  
Peoria, Illinois 61604

May 10, 1983

Dear Mr. Lyons;

Please send us an additional lyophil of NRRL B-15356,  
CNC#1533 Escherichia coli pSY 2501 so that we can complete  
equivalecy testing of this strain. Thanking you in advance.

Sincerely,

CETUS CORPORATION

Angela Belt  
Curator-Culture Collection

443

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO  
Angela Belt  
Cetus Corporation  
600 Bancroft Way  
Berkeley, CA 46710

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT  
issued pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITORY AUTHORITY  
identified at the bottom of this page

NAME AND ADDRESS  
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the  
DEPOSITOR:

CMCC# 1533 Escherichia coli  
PSY 2501

Accession number given by the  
INTERNATIONAL DEPOSITORY AUTHORITY:

NRRL B-15356

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

a scientific description

a proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above,  
which was received by it on March 30, 83 (date of the original deposit)<sup>1</sup>

IV. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Agricultural Research Culture  
Collection (NRRL)  
International Depository Authority  
Address: 1815 N. University Street  
Peoria, Illinois 61604 U.S.A.

Signature(s) of person(s) having the power  
to represent the International Depository  
Authority or of authorized official(s):

Date: *Albert Lyons*  
*March 30, 1983*

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired; where a deposit made outside the Budapest Treaty after the acquisition of the status of international depositary authority is converted into a deposit under the Budapest Treaty, such date is the date on which the microorganism was received by the international depositary authority.

# Exhibit B



## AMERICAN TYPE CULTURE COLLECTION

12301 Parklawn Drive, Rockville, Maryland 20852, U.S.A.

### BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

#### INTERNATIONAL FORM

#### VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

TO: Cetus Corporation  
ADDRESS: 1400 - 53rd Street  
Emeryville, California 94608  
Attention: Angeia Belt

DEPOSITOR: \_\_\_\_\_  
ADDRESS: \_\_\_\_\_  
\_\_\_\_\_

#### Identification of the Microorganism(s)

Escherichia coli mm294-1, cmcc#1872  
Escherichia coli pLW55 (mm294-1), cmcc=1865  
\* Escherichia coli psv2501 (mm294-1), cmcc= 1494

#### ATCC Accession Designation(s)

39515  
39516  
39517

Date of the Deposit or of the Transfer\*

November 18, 1983

The viability of the microorganism(s) identified above was tested on December 1, 1983. On that date, the said microorganism(s) was(were):

XX viable

no longer viable

CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED (complete only if test was negative): \_\_\_\_\_

INTERNATIONAL DEPOSITORY AUTHORITY:

American Type Culture Collection  
12301 Parklawn Drive  
Rockville, Maryland 20852, U.S.A.

Signature of person having the power to represent the ATCC:

Bobbie A. Brandon  
(Mrs.) Bobbie A. Brandon, Head Professional Services Department

Date: December 2, 1983

\*In cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.



AMERICAN TYPE CULTURE COLLECTION  
12301 Parklawn Drive, Rockville, Maryland 20852, U.S.A.

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO: Cetus Corporation  
1400 - 53rd Street  
Emeryville, California 94608  
Attention: Angela Belt

RECEIPT IN THE CASE OF AN  
ORIGINAL DEPOSIT issued  
pursuant to Rule 7.3 by the  
INTERNATIONAL DEPOSITORY AUTHORITY

Name and Address of Depositor  
or His/Her Attorney

Identification reference given by the  
DEPOSITOR:

Accession number given by the ATCC:

<u>Escherichia coli</u> mm294-1, cmcc#1872	39515
<u>Escherichia coli</u> pLW55 (mm294-1), cmcc#1865	39516
<u>Escherichia coli</u> psy2501 (mm294-1), cmcc# 1494	39517

The microorganism(s) identified above was(were) accompanied by:

a scientific description

a proposed taxonomic designation: \_\_\_\_\_

The microorganism(s) identified above was(were) received on November 18, 1983  
by this International Depository Authority and has been accepted.

Name of International Depository Authority

American Type Culture Collection

Signature of person having the power  
to represent the American Type  
Culture Collection.

Bobbie A. Brandon

(Mrs.) Bobbie A. Brandon

Address: 12301 Parklawn Drive

Rockville, Md. 20852 U.S.A.

Date: December 2, 1983



## AMERICAN TYPE CULTURE COLLECTION

12301 Parklawn Drive  
Rockville, Maryland 20852 U.S.A.  
Tel.: 301-881-2600 Telex: 908-768

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE  
DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

- \*1. Name of microorganism or culture Escherichia coli psy2501 (mm294-1)
2. Strain designation given by the depositor (number, symbols, etc.)  
cmcc# 1494; psy2501(mm294-1) 3951-
3. Is this strain being deposited under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure? YES
- Name and Address of Depositor CETUS CORPORATION  
1400 53rd STREET  
EMERYVILLE, CALIFORNIA 94608
4. Is this deposit a mixture of microorganisms? NO
5. Details and conditions necessary for the cultivation of the strain for its storage and for testing its viability and also, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence. Grow at 35C in 2% Trypticase soybean meal  
thiamine, and without glucose. Include 50ug/ml Ampicillin in medium  
(recipe attached)
6. An indication of the properties of the strain which are or may be dangerous to health or the environment, or an indication that the depositor is not aware of such properties.  
unaware of hazards
- \*7. It is recommended that sufficient description be provided to allow the ATCC to confirm that the strain deposited generally conforms to that which the depositor states is being deposited (i.e., gram negative rod).  
gram negative rod
- \*8. Is this strain zoopathogenic? no phytopathogenic? no

\*The answers to these questions are recommended but not required.

FOR ATCC USE ONLY
ATCC NO. _____
DATE CULTURE RECEIVED _____
DATE VIABILITY TEST COMPLETED _____

**BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF  
MICROORGANISMS FOR THE  
PURPOSES OF PATENT PROCEDURE<sup>\*1</sup>**

Done at Budapest on April 28, 1977

**TABLE OF CONTENTS\*\***

*Introductory Provisions*

- Article 1: Establishment of a Union
- Article 2: Definitions

*Chapter I: Substantive Provisions*

- Article 3: Recognition and Effect of the Deposit of Microorganisms
- Article 4: New Deposit
- Article 5: Export and Import Restrictions
- Article 6: Status of International Depositary Authority
- Article 7: Acquisition of the Status of International Depositary Authority
- Article 8: Termination and Limitation of the Status of International Depositary Authority
- Article 9: Intergovernmental Industrial Property Organizations

*Chapter II: Administrative Provisions*

- Article 10: Assembly
- Article 11: International Bureau
- Article 12: Regulations

*Chapter III: Revision and Amendment*

- Article 13: Revision of the Treaty
- Article 14: Amendment of Certain Provisions of the Treaty

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\* Official English title.

Source: International Bureau of WIPO.

Note: This Treaty was signed on April 28, 1977, at Budapest, by the following States: Bulgaria, Denmark, Finland, France, Germany (Federal Republic of), Hungary, Italy, Netherlands, Norway, Spain, Switzerland, United Kingdom, United States of America; it will remain open for signature at Budapest until December 31, 1977.

\*\* This Table of Contents is added for the convenience of the reader (*Editor's Note*).

<sup>1</sup> Reprinted from the text published by the World Intellectual Property Organization (WIPO).

***Chapter IV: Final Provisions***

- Article 15: Becoming Party to the Treaty
- Article 16: Entry Into Force of the Treaty
- Article 17: Denunciation of the Treaty
- Article 18: Signature and Languages of the Treaty
- Article 19: Deposit of the Treaty; Transmittal of Copies; Registration of the Treaty
- Article 20: Notifications

**INTRODUCTORY PROVISIONS****Article 1****Establishment of a Union**

The States party to this Treaty (hereinafter called "the Contracting States") constitute a Union for the international recognition of the deposit of microorganisms for the purposes of patent procedure.

**Article 2****Definitions**

For the purposes of this Treaty and the Regulations:

- (i) references to a "patent" shall be construed as references to patents for inventions, inventors' certificates, utility certificates, utility models, patents or certificates of addition, inventors' certificates of addition, and utility certificates of addition;
- (ii) "deposit of a microorganism" means, according to the context in which these words appear, the following acts effected in accordance with this Treaty and the Regulations; the transmittal of a microorganism to an international depositary authority, which receives and accepts it, or the storage of such a microorganism by the international depositary authority, or both the said transmittal and the said storage;
- (iii) "patent procedure" means any administrative or judicial procedure relating to a patent application or a patent;
- (iv) "publication for the purposes of patent procedure" means the official publication, or the official laying open for public inspection, of a patent application or a patent;

(v) "Intergovernmental industrial property organization" means an organization that has filed a declaration under Article 9(1);

(vi) "industrial property office" means an authority of a Contracting State or an intergovernmental industrial property organization competent for the grant of patents;

(vii) "depository institution" means an institution which provides for the receipt, acceptance and storage of microorganisms and the furnishing of samples thereof;

(viii) "international depositary authority" means a depository institution which has acquired the status of international depositary authority as provided in Article 7;

(ix) "depositor" means the natural person or legal entity transmitting a microorganism to an international depositary authority, which receives and accepts it, and any successor in title of the said natural person or legal entity;

(x) "Union" means the Union referred to in Article 1;

(xi) "Assembly" means the Assembly referred to in Article 10;

(xii) "Organization" means the World Intellectual Property Organization;

(xiii) "International Bureau" means the International Bureau of the Organization and, as long as it subsists, the United International Bureaux for the Protection of Intellectual Property (BIRPI);

(xiv) "Director General" means the Director General of the Organization;

(xv) "Regulations" means the Regulations referred to in Article 12.

## CHAPTER I

### SUBSTANTIVE PROVISIONS

#### Article 3

##### **Recognition and Effect of the Deposit of Microorganisms**

(1) (a) Contracting States which allow or require the deposit of microorganisms for the purposes of patent procedure shall recognize, for such purposes, the deposit of a microorganism with any international depositary authority. Such recognition shall include the recognition of the fact and date of the deposit as indicated by the international depositary authority as well as the recognition of the fact that what is furnished as a sample is a sample of the deposited microorganism.

(b) Any contracting State may require a copy of the receipt of the deposit referred to in subparagraph (a), issued by the international depositary authority.

(2) As far as matters regulated in this Treaty and the Regulations are concerned, no Contracting State may require compliance with requirements different from or additional to those which are provided in this Treaty and the Regulations.

#### Article 4

##### **New Deposit**

(1) (a) Where the international depositary authority cannot furnish samples of the deposited microorganism for any reason, in particular,

(i) where such microorganism is no longer viable, or

(ii) where the furnishing of samples would require that they be sent abroad and the sending or the receipt of the samples abroad is prevented by export or import restrictions,

that authority shall, promptly after having noted its inability to furnish samples, notify the depositor of such inability, indicating the cause thereof, and the depositor, subject to paragraph (2) and

as provided in this paragraph, shall have the right to make a new deposit of the microorganism which was originally deposited.

(b) The new deposit shall be made with the international depositary authority with which the original deposit was made, provided that:

(i) it shall be made with another international depositary authority where the institution with which the original deposit was made has ceased to have the status of international depositary authority, either entirely or in respect of the kind of microorganism to which the deposited microorganism belongs, or where the international depositary authority with which the original deposit was made discontinues, temporarily or definitively, the performance of its functions in respect of deposited microorganisms;

(ii) it may be made with another international depositary authority in the case referred to in subparagraph (a)(ii).

(c) Any new deposit shall be accompanied by a statement signed by the depositor alleging that the newly deposited microorganism is the same as that originally deposited. If the allegation of the depositor is contested, the burden of proof shall be governed by the applicable law.

(d) Subject to subparagraphs (a) to (c) and (e), the new deposit shall be treated as if it had been made on the date on which the original deposit was made where all the preceding statements concerning the viability of the originally deposited microorganism indicated that the microorganism was viable and where the new deposit was made within three months after the date on which the depositor received the notification referred to in subparagraph (a).

(e) Where subparagraph (b)(i) applies and the depositor does not receive the notification referred to in subparagraph (a) within six months after the date on which the termination, limitation or discontinuance referred to in subparagraph (b)(i) was published by the International Bureau, the three-month time limit referred to in subparagraph (d) shall be counted from the date of the said publication.

(2) The right referred to in paragraph (1)(a) shall not exist where the deposited microorganism has been transferred to another

international depositary authority as long as that authority is in a position to furnish samples of such microorganism.

### **Article 5**

#### **Export and Import Restrictions**

Each Contracting State recognizes that it is highly desirable that, if and to the extent to which the export from or import into its territory of certain kinds of microorganisms is restricted, such restriction should apply to microorganisms deposited, or destined for deposit, under this Treaty only where the restriction is necessary in view of national security or the dangers for health or the environment.

### **Article 6**

#### **Status of International Depository Authority**

(1) In order to qualify for the status of international depositary authority, any depositary institution must be located on the territory of a Contracting State and must benefit from assurances furnished by that State to the effect that the said institution complies and will continue to comply with the requirements specified in paragraph (2). The said assurances may be furnished also by an intergovernmental industrial property organization; in that case, the depositary institution must be located on the territory of a State member of the said organization.

(2) The depositary institution must, in its capacity of international depositary authority;

- (i) have a continuous existence;
- (ii) have the necessary staff and facilities, as prescribed in the Regulations, to perform its scientific and administrative tasks under this Treaty;
- (iii) be impartial and objective;
- (iv) be available, for the purposes of deposit, to any depositor under the same conditions;
- (v) accept for deposit any or certain kinds of microorganisms, examine their viability and store them, as prescribed in the Regulations.

(vi) issue a receipt to the depositor, and any required viability statement, as prescribed in the Regulations;

(vii) comply, in respect of the deposited microorganisms, with the requirement of secrecy, as prescribed in the Regulations;

(viii) furnish samples of any deposited microorganism under the conditions and in conformity with the procedure prescribed in the Regulations.

(3) The Regulations shall provide the measure to be taken:

(i) where an international depositary authority discontinues, temporarily or definitively, the performance of its functions in respect of deposited microorganisms or refuses to accept any of the kinds of microorganisms which it should accept under the assurances furnished;

(ii) in case of the termination or limitation of the status of international depositary authority of an international depositary authority.

## Article 7

### Acquisition of the Status of International Depositary Authority

(1)(a) A depositary institution shall acquire the status of international depositary authority by virtue of a written communication addressed to the Director General by the Contracting State on the territory of which the depositary institution is located and including a declaration of assurances to the effect that the said institution complies and will continue to comply with the requirements specified in Article 6(2). The said status may be acquired also by virtue of a written communication addressed to the Director General by an intergovernmental industrial property organization and including the said declaration.

(b) The communication shall also contain information on the depositary institution as provided in the Regulations and may indicate the date on which the status of international depositary authority should take effect.

(2)(a) If the Director General finds that the communication includes the required declaration and that all the required informa-

tion has been received, the communication shall be promptly published by the International Bureau.

(b) The status of international depositary authority shall be acquired as from the date of publication of the communication or, where a date has been indicated under paragraph (1)(b) and such date is later than the date of publication of the communication, as from such date.

(3) The details of the procedure under paragraphs (1) and (2) are provided in the Regulations.

## Article 8

### Termination and Limitation of the Status of International Depositary Authority

(1)(a) Any Contracting State or any intergovernmental industrial property organization may request the Assembly to terminate, or to limit to certain kinds of microorganisms, any authority's status of international depositary authority on the ground that the requirements specified in Article 6 have not been or are no longer complied with. However, such a request may not be made by a Contracting State or intergovernmental industrial property organization in respect of an international depositary authority for which it has made the declaration referred to in Article 7(1)(a).

(b) Before making the request under subparagraph (a), the Contracting State or the intergovernmental industrial property organization shall, through the intermediary of the Director General, notify the reasons for the proposed request to the Contracting State or the intergovernmental industrial property organization which has made the communication referred to in Article 7(1) so that that State or organization may, within six months from the date of the said notification, take appropriate action to obviate the need for making the proposed request.

(c) Where the Assembly finds that the request is well founded, it shall decide to terminate, or to limit to certain kinds of microorganisms, the status of international depositary authority of the authority referred to in subparagraph (a). The decision of the Assembly shall require that a majority of two-thirds of the votes cast be in favor of the request.

(2)(a) The Contracting State or intergovernmental industrial property organization having made the declaration referred to in Article 7(1)(a) may, by a communication addressed to the Director General, withdraw its declaration either entirely or in respect only of certain kinds of microorganisms and in any event shall do so when and to the extent that its assurances are no longer applicable.

(b) Such a communication shall, from the date provided for in the Regulations, entail, where it relates to the entire declaration, the termination of the status of international depositary authority or, where it relates only to certain kinds of microorganisms, a corresponding limitation of such status.

(3) The details of the procedure under paragraphs (1) and (2) are provided in the Regulations.

## Article 9

### Intergovernmental Industrial Property Organizations

(1)(a) Any intergovernmental organization to which several States have entrusted the task of granting regional patents and of which all the member States are members of the International (Paris) Union for the Protection of Industrial Property may file with the Director General a declaration that it accepts the obligation of recognition provided for in Article 3(1)(a), the obligation concerning the requirements referred to in Article 3(2) and all the effects of the provisions of this Treaty and the Regulations applicable to intergovernmental industrial property organizations. If filed before the entry into force of this Treaty according to Article 16(1), the declaration referred to in the preceding sentence shall become effective on the date of the said entry into force. If filed after such entry into force, the said declaration shall become effective three months after its filing unless a later date has been indicated in the declaration. In the latter case, the declaration shall take effect on the date thus indicated.

(b) The said organization shall have the right provided for in Article 3(1)(b).

(2) Where any provision of this Treaty or of the Regulations affecting intergovernmental industrial property organizations is revised or amended, any intergovernmental industrial property organization may withdraw its declaration referred to in paragraph

(1) by notification addressed to the Director General. The withdrawal shall take effect:

(i) where the notification has been received before the date on which the revision or amendment enters into force, on that date;

(ii) where the notification has been received after the date referred to in (i), on the date indicated in the notification or, in the absence of such indication, three months after the date on which the notification was received.

(3) In addition to the case referred to in paragraph (2), any intergovernmental industrial property organization may withdraw its declaration referred to in paragraph (1)(a) by notification addressed to the Director General. The withdrawal shall take effect two years after the date on which the Director General has received the notification. No notification of withdrawal under this paragraph shall be receivable during a period of five years from the date on which the declaration took effect.

(4) The withdrawal referred to in paragraph (2) or (3) by an intergovernmental industrial property organization whose communication under Article 7(1) has led to the acquisition of the status of international depositary authority by a depositary institution shall entail the termination of such status one year after the date on which the Director General has received the notification of withdrawal.

(5) Any declaration referred to in paragraph (1)(a), notification of withdrawal referred to in paragraph (2) or (3), assurances furnished under Article 6(1), second sentence, and included in a declaration made in accordance with Article 7(1)(a), request made under Article 8(1) and communication of withdrawal referred to in Article 8(2) shall require the express previous approval of the supreme governing organ of the intergovernmental industrial property organization whose members are all the States members of the said organization and in which decisions are made by the official representatives of the governments of such States.

**CHAPTER II**  
**ADMINISTRATIVE PROVISIONS**

**Article 10**

**Assembly**

(1)(a) The Assembly shall consist of the Contracting States.

(b) Each Contracting State shall be represented by one delegate, who may be assisted by alternate delegates, advisors, and experts.

(c) Each intergovernmental industrial property organization shall be represented by special observers in the meetings of the Assembly and any committee and working group established by the Assembly.

(d) Any State not member of the Union which is a member of the Organization or of the International (Paris) Union for the Protection of Industrial Property and any intergovernmental organization specialized in the field of patents other than an intergovernmental industrial property organization as defined in Article 2(v) may be represented by observers in the meetings of the Assembly and, if the Assembly so decides, in the meetings of any committee or working group established by the Assembly.

(2)(a) The Assembly shall:

(i) deal with all matters concerning the maintenance and development of the Union and the implementation of this Treaty;

(ii) exercise such rights and perform such tasks as are specially conferred upon it or assigned to it under this Treaty;

(iii) give directions to the Director General concerning the preparations for revision conferences;

(iv) review and approve the reports and activities of the Director General concerning the Union, and give him all necessary instructions concerning matters within the competence of the Union;

(v) establish such committees and working groups as it deems appropriate to facilitate the work of the Union;

(vi) determine, subject to paragraph (1)(d), which States other than Contracting States, which intergovernmental organizations other than intergovernmental industrial property organizations as defined in Article 2(v) and which international non-governmental organizations shall be admitted to its meetings as observers and to what extent international depositary authorities shall be admitted to its meetings as observers;

(vii) take any other appropriate action designed to further the objectives of the Union;

(viii) perform such other functions as are appropriate under this Treaty.

(b) With respect to matters which are of interest also to other Unions administered by the Organization, the Assembly shall make its decisions after having heard the advice of the Coordination Committee of the Organization.

(3) A delegate may represent, and vote in the name of, one State only.

(4) Each Contracting State shall have one vote.

(5) (a) One half of the Contracting States shall constitute a quorum.

(b) In the absence of the quorum, the Assembly may make decisions but, with the exception of decisions concerning its own procedure, all such decisions shall take effect only if the quorum and the required majority are attained through voting by correspondence as provided in the Regulations.

(6) (a) Subject to Articles 8(1)(c), 12(4) and 14(2)(b), the decisions of the Assembly shall require a majority of the votes cast.

(b) Abstentions shall not be considered as votes.

(7) (a) The Assembly shall meet once in every third calendar year in ordinary session upon convocation by the Director General, preferably during the same period and at the same place as the General Assembly of the Organization.

(b) The Assembly shall meet in extraordinary session upon convocation by the Director General, either on his own initiative or at the request of one fourth of the Contracting States.

(8) The Assembly shall adopt its own rules of procedure.

**Article 11**  
**International Bureau**

(1) The International Bureau shall:

(i) perform the administrative tasks concerning the Union, in particularly such tasks as are specifically assigned to it under this Treaty and the Regulations or by the Assembly;

(ii) provide the secretariat of revision conferences of the Assembly, of committees and working groups established by the Assembly, and of any other meeting convened by the Director General and dealing with matters of concern to the Union.

(2) The Director General shall be the chief executive of the Union and shall represent the Union.

(3) The Director General shall convene all meetings dealing with matters of concern to the Union.

(4)(a) The Director General and any staff member designated by him shall participate, without the right to vote, in all meetings of the Assembly, the committees and working groups established by the Assembly, and any other meeting convened by the Director General and dealing with matters of concern to the Union.

(b) The Director General, or a staff member designated by him, shall be ex officio secretary of the Assembly, and of the committees, working groups and other meetings referred to in subparagraph (a).

(5)(a) The Director General shall, in accordance with the directions of the Assembly, make the preparations for revision conferences.

(b) The Director General may consult with intergovernmental and international non-governmental organizations concerning the preparations for revision conferences.

(c) The Director General and persons designated by him shall take part, without the right to vote, in the discussions at revision conferences.

(d) The Director General, or a staff member designated by him, shall be ex officio secretary of any revision conference.

**Article 12**

**Regulations**

(1) The Regulations provide rules concerning:

(i) matters in respect of which this Treaty expressly refers to the Regulations or expressly provides that they are or shall be prescribed;

(ii) any administrative requirements, matters or procedures;

(iii) any details useful in the implementation of this Treaty.

(2) The Regulations adopted at the same time as this Treaty are annexed to this Treaty.

(3) The Assembly may amend the Regulations.

(4)(a) Subject to subparagraph (b); adoption of any amendment of the Regulations shall require two-thirds of the votes cast.

(b) Adoption of any amendment concerning the furnishing of samples of deposited microorganisms by the international depositary authorities shall require that no Contracting State vote against the proposed amendment.

(5) In the case of conflict between the provisions of this Treaty and those of the Regulations, the provisions of this Treaty shall prevail.

**CHAPTER III**

**REVISION AND AMENDMENT**

**Article 13**

**Revision of the Treaty**

(1) This Treaty may be revised from time to time by conferences of the Contracting States.

(2) The convocation of any revision conference shall be decided by the Assembly.

(3) Articles 10 and 11 may be amended either by a revision conference or according to Article 14.

**Article 14****Amendment of Certain Provisions of the Treaty**

(1)(a) Proposals under this Article for the amendment of Articles 10 and 11 may be initiated by any Contracting State or by the Director General.

(b) Such proposals shall be communicated by the Director General to the Contracting States at least six months in advance of their consideration by the Assembly.

(2)(a) Amendments to the Articles referred to in paragraph (1) shall be adopted by the Assembly.

(b) Adoption of any amendment to Article 10 shall require four-fifths of the votes cast; adoption of any amendment to Article 11 shall require three-fourths of the votes cast.

(3)(a) Any amendment to the Articles referred to in paragraph (1) shall enter into force one month after written notifications of acceptance, effected in accordance with their respective constitutional processes, have been received by the Director General from three-fourths of the Contracting States members of the Assembly at the time the Assembly adopted the amendment.

(b) Any amendment to the said Articles thus accepted shall bind all the Contracting States which were Contracting States at the time the amendment was adopted by the Assembly, provided that any amendment creating financial obligations for the said Contracting States or increasing such obligations shall bind only those Contracting States which have notified their acceptance of such amendment.

(c) Any amendment which has been accepted and which has entered into force in accordance with subparagraph (a) shall bind all States which become Contracting States after the date on which the amendment was adopted by the Assembly.

462

**CHAPTER IV****FINAL PROVISIONS****Article 15****Becoming Party to the Treaty**

(1) Any State member of the International (Paris) Union for the Protection of Industrial Property may become party to this Treaty by:

(i) signature followed by the deposit of an instrument of ratification, or

(ii) deposit of an instrument of accession.

(2) Instruments of ratification or accession shall be deposited with the Director General.

**Article 16****Entry Into Force of the Treaty**

(1) This Treaty shall enter into force, with respect to the first five States which have deposited their instruments of ratification or accession, three months after the date on which the fifth instrument of ratification or accession has been deposited.

(2) This Treaty shall enter into force with respect to any other State three months after the date on which that State has deposited its instrument of ratification or accession unless a later date has been indicated in the instrument of ratification or accession. In the latter case, this Treaty shall enter into force with respect to that State on the date thus indicated.

**Article 17****Denunciation of the Treaty**

(1) Any Contracting State may denounce this Treaty by notification addressed to the Director General.

(2) Denunciation shall take effect two years after the day on which the Director General has received the notification.

(3) The right of denunciation provided for in paragraph (1)

App 3-660

**APPENDIX 3**

shall not be exercised by any Contracting State before the expiration of five years from the date on which it becomes party to this Treaty.

(4) The denunciation of this Treaty by a Contracting State that has made a declaration referred to in Article 7(1)(a) with respect to a depositary institution which thus acquired the status of international depositary authority shall entail the termination of such status one year after the day on which the Director General received the notification referred to in paragraph (1).

**Article 18**

**Signature and Languages of the Treaty**

(1)(a) This Treaty shall be signed in a single original in the English and French languages, both texts being equally authentic.

(b) Official texts of this Treaty shall be established by the Director General, after consultation with the interested Governments and within two months from the date of signature of this Treaty, in the other languages in which the Convention Establishing the World Intellectual Property Organization was signed.

(c) Official texts of this Treaty shall be established by the Director General, after consultation with the interested Governments, in the Arabic, German, Italian, Japanese and Portuguese languages, and such other languages as the Assembly may designate.

(2) This Treaty shall remain open for signature at Budapest until December 31, 1977.

**Article 19**

**Deposit of the Treaty; Transmittal of Copies;  
Registration of the Treaty**

(1) The original of this Treaty, when no longer open for signature, shall be deposited with the Director General.

(2) The Director General shall transmit two copies, certified by him, of this Treaty and the Regulations to the Governments of all the States referred to in Article 15(1), to the intergovernmental organizations that may file a declaration under Article 9(1)(a) and, on request, to the Government of any other State.

(3) The Director General shall register this Treaty with the Secretariat of the United Nations.

(4) The Director General shall transmit two copies, certified by him, of any amendment to this Treaty and to the Regulations to all Contracting States, to all intergovernmental industrial property organizations and, on request, to the Government of any other State and to any other intergovernmental organization that may file a declaration under Article 9(1)(a).

## Article 20

### Notifications

The Director General shall notify the Contracting States, the intergovernmental industrial property organizations and those States not members of the Union which are members of the International (Paris) Union for the Protection of Industrial Property of:

- (i) signatures under Article 18;
- (ii) deposits of instruments of ratification or accession under Article 15(2);
- (iii) declarations filed under Article 9(1)(a) and notifications of withdrawal under Article 9(2) or (3);
- (iv) the date of entry into force of this Treaty under Article 16(1);
- (v) the communications under Articles 7 and 8 and the decisions under Article 8;
- (vi) acceptance of amendments to this Treaty under Article 14(3);
- (vii) any amendment of the Regulations;
- (viii) the dates on which amendments to the Treaty or the Regulations enter into force;
- (ix) denunciations received under Article 17.

**REGULATIONS<sup>1</sup>****Under the Budapest Treaty on the International Recognition  
of the Deposit of Microorganisms for the Purposes  
of Patent Procedure****TABLE OF CONTENTS\****Rule 1: Abbreviated Expressions and Interpretation of the Word  
"Signature"*

- 1.1 "Treaty"
- 1.2 "Article"
- 1.3 "Signature"

*Rule 2: International Depositary Authorities*

- 2.1 Legal Status
- 2.2 Staff and Facilities
- 2.3 Furnishing of Samples

*Rule 3: Acquisition of the Status of International Depositary Au-  
thority*

- 3.1 Communication
- 3.2 Processing of the Communication
- 3.3 Extension of the List of Kinds of Microorganisms Ac-  
cepted

*Rule 4: Termination or Limitation of the Status of International  
Depositary Authority*

- 4.1 Request; Processing of Request
- 4.2 Communication; Effective Date; Processing of Communi-  
cation
- 4.3 Consequences for Deposits

*Rule 5: Defaults by the International Depositary Authority*

- 5.1 Discontinuance of Performance of Functions in Respect  
of Deposited Microorganisms
- 5.2 Refusal to Accept Certain Kinds of Microorganisms

*Rule 6: Making the Original Deposit or New Deposit*

- 6.1 Original Deposit

\* This Table of Contents is added for the convenience of the reader  
(Editor's note).

<sup>1</sup> Reprinted from the text published by the World Intellectual Property  
Organization (WIPO).

## 6.2 New Deposit

## 6.3 Requirements of the International Depositary Authority

*Rule 7: Receipt*

- 7.1 Issuance of Receipt
- 7.2 Form; Languages; Signature
- 7.3 Contents in the Case of the Original Deposit
- 7.4 Contents in the Case of the New Deposit
- 7.5 Receipt in the Case of Transfer
- 7.6 Communication of the Scientific Description and/or Proposed Taxonomic Designation

*Rule 8: Later Indication or Amendment of the Scientific Description and/or Proposed Taxonomic Designation*

- 8.1 Communication
- 8.2 Attestation

*Rule 9: Storage of Microorganisms*

- 9.1 Duration of the Storage
- 9.2 Secrecy

*Rule 10: Viability Test and Statement*

- 10.1 Obligation to Test
- 10.2 Viability Statement

*Rule 11: Furnishing of Samples*

- 11.1 Furnishing of Samples to Interested Industrial Property Offices
- 11.2 Furnishing of Samples to or with the Authorization of the Depositor
- 11.3 Furnishing of Samples to Parties Legally Entitled
- 11.4 Common Rules

*Rule 12: Fees*

- 12.1 Kinds and Amounts
- 12.2 Change in the Amounts

*Rule 13: Publication by the International Bureau*

- 13.1 Form of Publication
- 13.2 Contents

*Rule 14: Expenses of Delegations*

- 14.1 Coverage of Expenses

*Rule 15: Absence of Quorum in the Assembly*

- 15.1 Voting by Correspondence

(Ref.59-3/85 Pub.055)

**Rule 1**

**Abbreviated Expressions and Interpretation  
of the Word "Signature"**

**1.1 "Treaty"**

In these Regulations, the word "Treaty" means the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure.

**1.2 "Article"**

In these Regulations, the word "Article" refers to the specified Article of the Treaty.

**1.3 "Signature"**

In these Regulations, whenever the word "signature" is used, it shall be understood that, where the law of the State on the territory of which an international depositary authority is located requires the use of a seal instead of a signature, the said word shall mean "seal" for the purposes of that authority.

**Rule 2**

**International Depositary Authorities**

**2.1 Legal Status**

Any international depositary authority may be a government agency, including any public institution attached to a public administration other than the central government, or a private entity.

**2.2 Staff and Facilities**

The requirements referred to in Article 6(2)(ii) shall include in particular the following:

(i) the staff and facilities of any international depositary authority must enable the said authority to store the deposited micro-organisms in a manner which ensures that they are kept viable and uncontaminated.

(ii) any international depositary authority must, for the storage of microorganisms, provide for sufficient safety measures to minimize the risk of losing microorganisms deposited with it.

**2.3 Furnishing of Samples**

The requirements referred to in Article 6(2)(viii) shall include in particular the requirement that any international depositary authority must furnish samples of deposited microorganisms in an expeditious and proper manner.

(Ref 59-3/85 Pub.055)

468

**Rule 3**

**Acquisition of the Status of International  
Depository Authority**

**3.1 Communication**

(a) The communication referred to in Article 7(1) shall be addressed to the Director General, in the case of a Contracting State, through diplomatic channels or, in the case of an intergovernmental industrial property organization, by its chief executive officer.

(b) The communication shall:

- (i) indicate the name and address of the depository institution to which the communication relates;
- (ii) contain detailed information as to the said institution's capacity to comply with the requirements specified in Article 6(2), including information on its legal status, scientific standing, staff and facilities;
- (iii) where the said depository institution intends to accept for deposit only certain kinds of microorganisms, specify such kinds;
- (iv) indicate the amount of any fees that the said institution will, upon acquiring the status of international depository authority, charge for storage, viability statements and furnishing of samples of microorganisms;
- (v) indicate the official language or languages of the said institution;
- (vi) where applicable, indicate the date referred to in Article 7(1)(b).

**3.2 Processing of the Communication**

If the communication complies with Article 7(1) and Rule 3.1, it shall be promptly notified by the Director General to all Contracting States and intergovernmental industrial property organizations and shall be promptly published by the International Bureau.

**3.3 Extension of the List of Kinds of Microorganisms Accepted**

The Contracting State or intergovernmental industrial prop-

(Rev.59-3.85 Pub.055)

469

erty organization having made the communication referred to in Article 7(1) may, at any time thereafter, notify the Director General that its assurances are extended to specified kinds of micro-organisms to which, so far, the assurances have not extended. In such a case, and as far as the additional kinds of microorganisms are concerned, Article 7 and Rules 3.1 and 3.2 shall apply, *mutatis mutandis*.

#### Rule 4

##### Termination or Limitation of the Status of International Depository Authority

###### 4.1 Request; Processing of Request

(a) The request referred to in Article 8(1)(a) shall be addressed to the Director General as provided in Rule 3.1(a).

(b) The request shall:

(i) indicate the name and address of the international depository authority concerned;

(ii) where it relates only to certain kinds of microorganisms, specify such kinds;

(iii) indicate in detail the facts on which it is based.

(c) If the request complies with paragraphs (a) and (b), it shall be promptly notified by the Director General to all Contracting States and intergovernmental industrial property organizations.

(d) Subject to paragraph (e), the Assembly shall consider the request not earlier than six and not later than eight months from the notification of the request.

(e) Where, in the opinion of the Director General, respect of the time limit provided for in paragraph (d) could endanger the interests of actual or potential depositors, he may convene the Assembly for a date earlier than the date of the expiration of the six-month period provided for in paragraph (d).

(f) If the Assembly decides to terminate, or to limit to certain kinds of microorganisms, the status of international depository authority, the said decision shall become effective three months after the date on which it was made.

**4.2 Communication; Effective Date; Processing of Communication**

(a) The communication referred to in Article 8(2)(a) shall be addressed to the Director General as provided in Rule 3.1(a).

(b) The communication shall:

(i) indicate the name and address of the international depositary authority concerned;

(ii) where it relates only to certain kinds of microorganisms, specify such kinds;

(iii) where the Contracting State or intergovernmental industrial property organization making the communication desires that the effects provided for in Article 8(2)(b) take place on a date later than at the expiration of three months from the date of the communication, indicate that later date.

(c) Where paragraph (b)(iii) applies, the effects provided for in Article 8(2)(b) shall take place on the date indicated under that paragraph in the communication; otherwise, they shall take place at the expiration of three months from the date of the communication.

(d) The Director General shall promptly notify all Contracting States and intergovernmental industrial property organizations of any communication received under Article 8(2) and of its effective date under paragraph (c). A corresponding notice shall be promptly published by the International Bureau.

**4.3 Consequences for Deposits**

In the case of a termination or limitation of the status of international depositary authority under Articles 8(1), 8(2), 9(4) or 17(f), Rule 5.1 shall apply, *mutatis mutandis*.

**Rule 5****Defaults by the International Depositary Authority****5.1 Discontinuance of Performance of Functions in Respect of Deposited Microorganisms**

(a) If any international depositary authority temporarily or definitively discontinues the performance of any of the tasks it should perform under the Treaty and these Regulations in relation

to any microorganisms deposited with it, the Contracting State or intergovernmental industrial property organization which, in respect of that authority, has furnished the assurances under Article 6(1) shall:

(i) ensure, to the fullest extent possible, that samples of all such microorganisms are transferred promptly and without deterioration or contamination from the said authority ("the defaulting authority") to another international depository authority ("the substitute authority");

(ii) ensure, to the fullest extent possible, that all mail or other communications addressed to the defaulting authority, and all files and other relevant information in the possession of that authority, in respect of the said microorganisms are promptly transferred to the substitute authority;

(iii) ensure, to the fullest extent possible, that the defaulting authority promptly notifies all depositors affected of the discontinuance of the performance of its functions and the transfers effected;

(iv) promptly notify the Director General of the fact and the extent of the discontinuance in question and of the measures which have been taken by the said Contracting State or intergovernmental industrial property organization under (i) to (iii).

(b) The Director General shall promptly notify the Contracting States and the intergovernmental industrial property organizations as well as the industrial property offices of the notification received under paragraph (a)(iv); the notification of the Director General and the notification received by him shall be promptly published by the International Bureau.

(c) Under the applicable patent procedure it may be required that the depositor shall, promptly after receiving the receipt referred to in Rule 7.5, notify to any industrial property office with which a patent application was filed with reference to the original deposit the new accession number given to the deposit by the substitute authority.

(d) The substitute authority shall retain in an appropriate form the accession number given by the defaulting authority, together with the new accession number.

(e) In addition to any transfer effected under paragraph (a) (i), the defaulting authority shall, upon request by the depositor, transfer a sample of any microorganism deposited with it to any international depositary authority indicated by the depositor other than the substitute authority, provided that the depositor pays any expenses to the defaulting authority resulting from the transfer of that sample. The depositor shall pay the fee for the storage of the said sample to the international depositary authority indicated by him.

(f) On the request of any depositor affected, the defaulting authority shall retain, as far as possible, samples of the microorganisms deposited with it.

#### *5.2 Refusal To Accept Certain Kinds of Microorganisms*

(a) If any international depositary authority refuses to accept for deposit any of the kinds of microorganisms which it should accept under the assurances furnished, the Contracting State or intergovernmental industrial property organization which, in respect of that authority, has made the declaration referred to in Article 7(1)(a) shall promptly notify the Director General of the relevant facts and the measures which have been taken.

(b) The Director General shall promptly notify the other Contracting States and intergovernmental industrial property organizations of the notification received under paragraph (a); the notification of the Director General and the notification received by him shall be promptly published by the International Bureau.

### **Rule 6**

#### **Making the Original Deposit or New Deposit**

##### *6.1 Original Deposit*

a. The microorganism transmitted by the depositor to the international depositary authority shall, except where Rule 6.2 applies, be accompanied by a written statement bearing the signature of the depositor and containing:

- i. an indication that the deposit is made under the Treaty;
- ii. the name and address of the depositor;
- iii. details of the conditions necessary for the cultivation of

(Ref.59-3/85 Pub.055)

the microorganism, for its storage and for testing its viability and also, where a mixture of microorganisms is deposited, descriptions of the components of the mixture and at least one of the methods permitting the checking of their presence;

(iv) an identification reference (number, symbols, etc.) given by the depositor to the microorganism;

(v) an indication of the properties of the microorganism which the international depositary authority cannot be expected to foresee but which are dangerous to health or the environment, particularly in the case of new microorganisms.

(b) It is strongly recommended that the written statement referred to in paragraph (a) should contain the scientific description and/or proposed taxonomic designation of the deposited microorganism.

#### 6.2 New Deposit

(a) Subject to paragraph (b), in the case of a new deposit made under Article 4, the microorganism transmitted by the depositor to the international depositary authority shall be accompanied by a copy of the receipt of the original deposit, a copy of the most recent statement concerning the viability of the microorganism originally deposited indicating that the microorganism is viable and a written statement bearing the signature of the depositor and containing:

(i) the indications referred to in Rule 6.1(a)(i) to (v);

(ii) a declaration stating the reason relevant under Article 4(1)(a) for making the new deposit, the statement required under Article 4(1)(c), and, where applicable, an indication of the date relevant under Article 4(1)(e);

(iii) where a scientific description and/or proposed taxonomic designation was/were indicated in connection with the original deposit, the most recent scientific description and/or proposed taxonomic designation as existing on the date relevant under Article 4(1)(e).

(b) Where the new deposit is made with the international depositary authority with which the original deposit was made, paragraph (a)(i) shall not apply.

*6.3 Requirements of the International Depositary Authority*

(a) Any international depositary authority may require that the microorganism be deposited in the form and quantity necessary for the purposes of the Treaty and these Regulations and be accompanied by a form established by such authority and duly completed by the depositor for the purposes of the administrative procedures of such authority.

(b) Any international depositary authority shall communicate any such requirements and any amendments thereof to the International Bureau.

**Rule 7**

**Receipt**

*7.1 Issuance of Receipt*

The international depositary authority shall issue to the depositor, in respect of each deposit of microorganism effected with it or transferred to it, a receipt in attestation of the fact that it has received and accepted the microorganism.

*7.2 Form; Languages; Signature*

(a) Any receipt referred to in Rule 7.1 shall be established on a form called an "international form," a model of which shall be established by the Director General in those languages which the Assembly shall designate.

(b) Any words or letters filled in in the receipt in characters other than those of the Latin alphabet shall also appear their in transliterated in characters of the Latin alphabet.

(c) The receipt shall bear the signature of the person or persons having the power to represent the international depositary authority or that of any other official of that authority duly authorized by the said person or persons.

*7.3 Contents in the Case of the Original Deposit*

Any receipt referred to in Rule 7.1 and issued in the case of an original deposit shall indicate that it is issued by the depositary institution in its capacity of international depositary authority under the Treaty and shall contain at least the following indications:

(Ref 59-3 85 Pub.055)

- (i) the name and address of the international depositary authority;
- (ii) the name and address of the depositor;
- (iii) the date of receipt of the microorganism by the international depositary authority;
- (iv) the identification reference (number, symbols, etc.) given by the depositor to the microorganism;
- (v) the accession number given by the international depositary authority to the deposit;
- (vi) where the written statement referred to in Rule 6.1(a) contains the scientific description and/or proposed taxonomic designation of the microorganism, a reference to that fact.

#### *7.4 Contents in the Case of the New Deposit*

Any receipt referred to in Rule 7.1 and issued in the case of a new deposit effected under Article 4 shall be accompanied by a copy of the receipt of the original deposit and a copy of the most recent statement concerning the viability of the microorganism originally deposited indicating that the microorganism is viable, and shall at least contain:

- (i) the indications referred to in Rule 7.3(i) to (v);
- (ii) an indication of the relevant reason and, where applicable, the relevant date as stated by the depositor in accordance with Rule 6.2(a)(ii);
- (iii) where Rule 6.2(a)(iii) applies, a reference to the fact that a scientific description and/or a proposed taxonomic designation has/have been indicated by the depositor;
- (iv) the accession number given to the original deposit.

#### *7.5 Receipt in the Case of Transfer*

The international depositary authority to which samples of microorganisms are transferred under Rule 5.1(a)(1) shall issue to the depositor, in respect of each deposit in relation with which a sample is transferred, a receipt indicating that it is issued by the depositary institution in its capacity of international depositary authority under the Treaty and containing at least:

- (i) the indications referred to in Rule 7.3(i) to (v);
- (ii) the name and address of the international depositary authority from which the transfer was effected;
- (iii) the accession number given by the international depositary authority from which the transfer was effected.

**7.6 *Communication of the Scientific Description and/or Proposed Taxonomic Designation***

On request of any party entitled to receive a sample of the deposited microorganism under Rules 11.1; 11.2 or 11.3, the international depositary authority shall communicate to such party the scientific description and/or proposed taxonomic designation referred to in Rules 7.3(vi) or 7.4(iii).

**Rule 8**

**Later Indication or Amendment of the Scientific Description and/or Proposed Taxonomic Designation**

**8.1 *Communication***

(a) Where, in connection with the deposit of a microorganism, the scientific description and/or taxonomic designation of the microorganism was/were not indicated, the depositor may later indicate or, where already indicated, may amend such description and/or designation.

(b) Any such later indication or amendment shall be made in a written communication, bearing the signature of the depositor, addressed to the international depositary authority and containing:

- (i) the name and address of the depositor;
- (ii) the accession number given by the said authority;
- (iii) the scientific description and/or proposed taxonomic designation of the microorganism;
- (iv) in the case of an amendment, the last preceding scientific description and/or proposed taxonomic designation.

**8.2 *Attestation***

The international depositary authority shall, on the request of

(Ref.59-3/85 Pub.055)

the depositor having made the communication referred to in Rule 8.1, deliver to him an attestation showing the data referred to in Rule 8.1(b)(i) to (iv) and the date of receipt of such communication.

### Rule 9

#### Storage of Microorganisms

##### 9.1 Duration of the Storage

Any microorganism deposited with an international depositary authority shall be stored by such authority, with all the care necessary to keep it viable and uncontaminated, for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the said authority and, in any case, for a period of at least 30 years after the date of the deposit.

##### 9.2 Secrecy

No international depositary authority shall give information to anyone whether a microorganism has been deposited with it under the Treaty. Furthermore, it shall not give any information to anyone concerning any microorganism deposited with it under the Treaty except to an authority, natural person or legal entity which is entitled to obtain a sample of the said microorganism under Rule 11 and subject to the same conditions as provided in that Rule.

### Rule 10

#### Viability Test and Statement

##### 10.1 Obligation to Test

The international depositary authority shall test the viability of each microorganism deposited with it:

- (i) promptly after any deposit referred to in Rule 6 or any transfer referred to in Rule 5.1;
- (ii) at reasonable intervals, depending on the kind of microorganism and its possible storage conditions, or at any time, if necessary for technical reasons;
- (iii) at any time, on the request of the depositor.

**10.2 Viability Statement**

(a) The international depositary authority shall issue a statement concerning the viability of the deposited microorganism:

(i) to the depositor, promptly after any deposit referred to in Rule 6 or any transfer referred to in Rule 5.1;

(ii) to the depositor, on his request, at any time after the deposit or transfer;

(iii) to any industrial property office, other authority, natural person or legal entity, other than the depositor, to whom or to which samples of the deposited microorganism were furnished in conformity with Rule 11, on his or its request, together with or at any time after such furnishing of samples.

(b) The viability statement shall indicate whether the microorganism is or is no longer viable and shall contain.

(i) the name and address of the international depositary authority issuing it;

(ii) the name and address of the depositor;

(iii) the date of the deposit of the microorganism and of the transfer, if any;

(iv) the accession number given by the said authority;

(v) the date of the test to which it refers;

(vi) information on the conditions under which the viability test has been performed, provided that the said information has been requested by the party to which the viability statement is issued and that the results of the test were negative.

(c) In the cases of paragraph (a)(ii) and (iii), the viability statement shall refer to the most recent viability test.

(d) As to form, languages and signature, Rule 7.2 shall apply, *mutatis mutandis*, to the viability statement.

(e) In the case of paragraph (a)(i) or where the request is made by an industrial property office, the issuance of the viability statement shall be free of charge. Any fee payable under Rule 12.1(a)(iii) in respect of any other viability statement shall be chargeable to the party requesting the statement and shall be paid before or at the time of making the request.

**Rule 11****Furnishing of Samples****11.1 Furnishing of Samples to Interested Industrial Property Offices**

Any international depositary authority shall furnish a sample of any deposited microorganism to the industrial property office of any Contracting State or of any intergovernmental industrial property organization, on the request of such office, provided that the request shall be accompanied by a declaration to the effect that:

- (i) an application referring to the deposit of that microorganism has been filed with that office for the grant of a patent and that the subject matter of that application involves the said microorganism or the use thereof;
- (ii) such application is pending before that office or has led to the grant of a patent;
- (iii) the sample is needed for the purposes of a patent procedure having effect in the said Contracting State or in the said organization or its member States;
- (iv) the said sample and any information accompanying or resulting from it will be used only for the purposes of the said patent procedure.

**11.2 Furnishing of Samples to or with the Authorization of the Depositor**

Any international depositary authority shall furnish a sample of any deposited microorganism:

- (i) to the depositor, on his request;
- (ii) to any authority, natural person or legal entity (hereinafter referred to as "the authorized party"), on the request of such party, provided that the request is accompanied by a declaration of the depositor authorizing the requested furnishing of a sample.

**11.3 Furnishing of Samples to Parties Legally Entitled**

(a) Any international depositary authority shall furnish a sample of any deposited microorganism to any authority, natural person or legal entity (hereinafter referred to as "the certified party"), on the request of such party, provided that the request is

made on a form whose contents are fixed by the Assembly and that on the said form the industrial property office certifies:

- (i) that an application referring to the deposit of that micro-organism has been filed with that office for the grant of a patent and that the subject matter of that application involves the said microorganism or the use thereof;
- (ii) that, except where the second phrase of (iii) applies, publication for the purposes of patent procedure has been effected by that office;
- (iii) either that the certified party has a right to a sample of the microorganism under the law governing patent procedure before that office and, where the said law makes the said right dependent on the fulfillment of certain conditions, that that office is satisfied that such conditions have actually been fulfilled or that the certified party has affixed his signature on a form before that office and that, as a consequence of the signature of the said form, the conditions for furnishing a sample to the certified party are deemed to be fulfilled in accordance with the law governing patent procedure before that office; where the certified party has the said right under the said law prior to publication for the purposes of patent procedure by the said office and such publication has not yet been effected, the certification shall expressly state so and shall indicate, by citing it in the customary manner, the applicable provision of the said law, including any court decision.

(b) In respect of patents granted and published by any industrial property office, such office may from time to time communicate to any international depositary authority lists of the accession numbers given by that authority to the deposits of the microorganisms referred to in the said patents. The international depositary authority shall, on the request of any authority, natural person or legal entity (hereinafter referred to as "the requesting party"), furnish to it a sample of any microorganism where the accession number has been so communicated. In respect of deposited microorganisms whose accession numbers have been so communicated, the said office shall not be required to provide the certification referred to in Rule 11.3(a).

#### 11.4 Common Rules

(a) Any request, declaration, certification or communication referred to in Rules 11.1, 11.2 and 11.3 shall be

(i) in English, French, Russian or Spanish where it is addressed to an international depositary authority whose official language is or whose official languages include English, French, Russian or Spanish, respectively, provided that, where it must be in Russian or Spanish, it may be instead filed in English or French and, if it is so filed, the International Bureau shall, on the request of the interested party referred to in the said Rules or the international depositary authority, establish, promptly and free of charge, a certified translation into Russian or Spanish;

(ii) in all other cases, it shall be in English or French, provided that it may be, instead, in the official language or one of the official languages of the international depositary authority.

(b) Notwithstanding paragraph (a), where the request referred to in Rule 11.1 is made by an industrial property office whose official language is Russian or Spanish, the said request may be in Russian or Spanish, respectively, and the International Bureau shall establish, promptly and free of charge, a certified translation into English or French, on the request of that office.

(c) Any request, declaration, certification or communication referred to in Rules 11.1, 11.2 and 11.3 shall be in writing, shall bear a signature and shall be dated.

(d) Any request, declaration or certification referred to in Rules 11.1, 11.2 and 11.3(a) shall contain the following indications:

(i) the name and address of the industrial property office making the request, of the authorized party or of the certified party, as the case may be;

(ii) the accession number given to the deposit;

(iii) in the case of Rule 11.1, the date and number of the application or patent referring to the deposit;

(iv) in the case of Rule 11.3(a), the indications referred to in (iii) and the name and address of the industrial property office which has made the certification referred to in the said Rule.

(e) Any request referred to in Rule 11.3(b) shall contain the following indications:

(i) the name and address of the requesting party;

(ii) the accession number given to the deposit.

(f) The container in which the sample furnished is placed shall be marked by the international depositary authority with the accession number given to the deposit and shall be accompanied by a copy of the receipt referred to in Rule 7.

(g) The international depositary authority having furnished a sample to any interested party other than the depositor shall promptly notify the depositor in writing of that fact, as well as of the date on which the said sample was furnished and of the name and address of the industrial property office, of the authorized party, of the certified party, or of the requesting party, to whom or to which the sample was furnished. The said notification shall be accompanied by a copy of the pertinent request, of any declarations submitted under Rules 11.1 or 11.2(ii) in connection with the said request, and of any forms or requests bearing the signature of the requesting party in accordance with Rule 11.3.

(h) The furnishing of samples referred to in Rule 11.1 shall be free of charge. Where the furnishing of samples is made under Rule 11.2 or 11.3, any fee payable under Rule 12.1(a)(iv) shall be chargeable to the depositor, to the authorized party, to the certified party or to the requesting party, as the case may be, and shall be paid before or at the time of making the said request.

## Rule 12

### Fees

#### 12.1 Kinds and Amounts

(a) Any international depositary authority may, with respect to the procedure under the Treaty and these Regulations, charge a fee:

- (i) for storage;
- (ii) for the attestation referred to in Rule 8.2;
- (iii) subject to Rule 10.2(e), first sentence, for the issuance of viability statements;
- (iv) subject to Rule 11.4(h), first sentence, for the furnishing of samples.

**13.2 Contents**

(a) At least in the first issue of each year of the said periodical, an up-to-date list of the international depositary authorities shall be published, indicating in respect of each such authority the kinds of microorganisms that may be deposited with it and the amount of the fees charged by it.

(b) Full information on any of the following facts shall be published once, in the first issue of the said periodical published after the occurrence of the fact:

(i) any acquisition, termination or limitation of the status of international depositary authority, and the measures taken in connection with that termination or limitation;

(ii) any extension referred to in Rule 3.3;

(iii) any discontinuance of the functions of an international depositary authority, any refusal to accept certain kinds of microorganisms, and the measures taken in connection with such discontinuance or refusal;

(iv) any change in the fees charged by an international depositary authority;

(v) any requirements communicated in accordance with Rule 6.3(b) and any amendments thereof.

**Rule 14****Expenses of Delegations****14.1 Coverage of Expenses**

The expenses of each delegation participating in any session of the Assembly and in any committee, working group or other meeting dealing with matters of concern to the Union shall be borne by the State or organization which has appointed it.

**Rule 15****Absence of Quorum in the Assembly****15.1 Voting by Correspondence**

(a) In the case provided for in Article 10(5)(b), the Director General shall communicate any decision of the Assembly (other

than decisions relating to the Assembly's own procedure) to the Contracting States which were not represented when the decision was made and shall invite them to express in writing their vote or abstention within a period of three months from the date of the communication.

(b) If, at the expiration of the said period, the number of Contracting States having thus expressed their vote or abstention attains the number of Contracting States which was lacking for attaining the quorum when the decision was made, that decision shall take effect provided that at the same time the required majority still obtains.

(b) The fee for storage shall be for the whole duration of the storage of the microorganism as provided in Rule 9.1.

(c) The amount of any fee shall not vary on account of the nationality or residence of the depositor or on account of the nationality or residence of the authority, natural person or legal entity requesting the issuance of a viability statement or furnishing of samples.

#### 12.2 *Change in the Amounts*

(a) Any change in the amount of the fees charged by any international depositary authority shall be notified to the Director General by the Contracting State or intergovernmental industrial property organization which made the declaration referred to in Article 7(1) in respect of that authority. The notification may, subject to paragraph (c), contain an indication of the date from which the new fees will apply.

(b) The Director General shall promptly notify all Contracting States and intergovernmental industrial property organizations of any notification received under paragraph (a) and of its effective date under paragraph (c); the notification of the Director General and the notification received by him shall be promptly published by the International Bureau.

(c) Any new fees shall apply as of the date indicated under paragraph (a), provided that, where the change consists of an increase in the amounts of the fees or where no date is so indicated, the new fees shall apply as from the thirtieth day following the publication of the change by the International Bureau.

### Rule 13

#### Publication by the International Bureau

##### 13.1 *Form of Publication*

Any publication by the International Bureau referred to in the Treaty or these Regulations shall be made in the monthly periodical of the International Bureau referred to in the Paris Convention for the Protection of Industrial Property.

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